BELGIAN ADVISORY COMMITTEE ON
Bioethics

Opinion no. 17 of 10 June 2002 on the "ethical aspects of self-tests to screen for the human immunodeficiency virus (HIV)"

Request for an opinion of 3 December 1999 from Mrs N. Maréchal, Minister for Youth Welfare and Health of the French Community

This request seeks the opinion of the Advisory Committee on Bioethics on the ethical aspects of the provision of self-tests to screen for HIV/AIDS following the initiative of the company Remed Pharma. The latter is thought to be preparing to place a product on the market called PREVENTOR VIH, presented as a rapid HIV test with interpretation of the initial result within fifteen minutes but explicitly requiring confirmation if it is positive. This product could be used in self-testing without medical support.

CONTENT OF THE OPINION

I. CONTEXT

Several aspects of the issue raised are specific to the HIV test. A certain number of more general aspects are, however, related to the availability (which will undoubtedly rapidly increase in the near future) of self-tests for other risks or illnesses.

Self-testing is defined as "a test that is requested and performed by the consumer on his or her own initiative - without the assistance of a doctor or another qualified person -, the result of which will be known to him or her alone and which will be interpreted by him or her alone, without the assistance of a doctor, and based on which, after personal interpretation of the result, he or she may undertake actions independently of third parties" (Van der Stappen and Ulencate, 1999). Self-tests are already available for a large number of illnesses (Van der Stappen and Ulencate, 1999). Genetic tests, which will one day be available, form a special category because they raise specific issues: these are susceptibility tests the results of which go beyond the level of the individual in that for example they entail consequences for the family (Englert, 2001).

There is a distinction to be made between monitoring tests and screening tests. The first are used in the context of a treatment in order to monitor changes in certain parameters and adjust the said treatment accordingly (e.g. checking of blood sugar levels in the case of diabetes, checking of blood pressure in the case of hypertension). The second are self-tests used to make certain diagnoses (e.g. pregnancy test) or to screen for certain conditions (e.g. prostate antigens).

While the role of monitoring tests is well-established in the literature, that of screening tests is more controversial. It is in this second group that self-tests to screen for HIV, discussed below, belong.

The phenomenon of self-tests is now widespread and will very likely spread further given the significance of the commercial interests at stake, and in the context of the growth of "predictive medicine", where people in good health have the possibility of acquiring information on their risks of developing certain illnesses in the future (de Vries, 1999). At the present time they are especially popular in the United States, where self-tests are marketed for various observations (e.g. consumption of certain products), illnesses and risks.

This opinion focuses on the use of self-tests to screen for HIV.

A. Epidemiology of AIDS and HIV infection in Belgium (Sasse et al., 2001)

AIDS is a potentially deadly epidemic and transmissible disease that was described for the first time in the early 1980s. It is caused by the human immunodeficiency virus (HIV).

The means of transmission are well-known: they take place through contact with contaminated blood, sperm or vaginal secretions. Infection occurs in the context of unprotected sexual intercourse, the use of contaminated needles (drug addicts), transmission from mother to child at birth and, very rarely in Belgium, through the transfusion of blood and its derived products. Prevention therefore consists of applying protective measures. The use of condoms during high-risk sexual intercourse and the use of uncontaminated needles for intravenous injections are therefore of paramount importance to avoid most infections.

From the start of the observations carried out by the reference laboratories (see below), a gradual increase in the number of new people infected (HIV-positive) recorded was observed, reaching up to 2.7 cases per day in 1992. A gradual decrease was observed thereafter. From 1997, the trend increased again slightly and reached an average increase of 2.6 new cases per day in 2000 (Van

de Velde, 2001). Since around 1986, we have only observed a slight fluctuation in the number of new infections and certainly not the exponential rise feared at first.

As at 31 December 2000, there was a total of 13,905 people in Belgium who had been diagnosed with an HIV infection, 42% of which were of Belgian nationality. In the majority of cases where the means of transmission is known, it is sexual contact.

After a certain time, symptoms of AIDS develop in infected patients. Since the early 1990s, we have observed a decrease in the incidence of new AIDS patients since the figure has fallen from approximately 250 to 100 per year (since 1997) and remains relatively stable, despite the continuous increase in the number of people infected (HIV-positive). This stabilisation can be explained by the improvement in anti-viral therapies. The cumulative total number of AIDS patients in Belgium up to and including the year 2000 amounted to 2,801. This figure is of the same order of magnitude as the figures for the Netherlands, Germany, Austria and the UK, but it is significantly lower than those for France and a number of Mediterranean countries.

B. Tests to screen for HIV infection

1. General observations

a. Importance of screening tests for HIV infection

The options for treating the infection have considerably improved, such that the progression from HIV infection to AIDS is increasingly delayed if continuous treatment is provided. This situation is reflected by decreasing numbers of AIDS-related deaths, despite the fact that the frequency of new infections remains relatively constant. Moreover, the chances of the treatment being effective increase based on the speed with which the treatment can be started following infection as this helps to better preserve the patient's immunological resources. The availability of treatment and the importance of its rapid administration make early diagnosis critical.

It should be noted that the effective treatment of the infection nevertheless has a drawback: according to a recent study, the resulting *sense* of security actually led to a reduction in the efforts made to avoid unsafe behaviour (de Wit et al., 2001).

Given the means of transmission of the virus, rapid diagnosis is also critical in terms of prevention. If the person infected is informed at an early stage, he or she can more quickly take steps to avoid infecting others.

The proportion of individuals presenting an increased risk of infection that undergo a screening test has not been accurately defined in Belgium. However, Sasse (2001) reports a decrease in the number of HIV tests performed since 1996, as well as a tendency to delay carrying out the test. According to US estimates, less than 40% of the people presenting an increased risk are tested in the United States (Berrios, et al., 1993; Phillips et al., 1997). It is furthermore estimated that approximately one-third of homosexual/bisexual men are unaware of their serological status (Stall et al., 1996).

In terms of public health, it important to be able to monitor the evolution of the epidemic within the population. To this end, it is necessary to have reliable data concerning the number of HIV-positive patients, the number of patients with AIDS and the (presumed) transmission method in order to tailor efforts to tackle the disease and to make the resources necessary for this purpose available.

b. Importance of the "HIV window" period

The usual tests are based on the detection of antibodies to certain virus antigens. Therefore, between the contact and the positive test, there is a period corresponding to the immune response.

In the beginning, this "HIV window" was relatively long (3 months), but the increasing sensitivity of these tests has reduced this period to approximately one month. In each case, it is necessary to take this factor into account in order to make good use of the test.

c. Risk of false positive and false negative results

It is necessary to make a distinction between screening tests and confirmation tests. Screening tests aim to detect the antibodies produced as a reaction to HIV in the blood (or urine) of the person being tested. To do this, HIV antigens are placed on a medium, and the medium is then placed in contact with the bodily fluid. After any antibodies present bind to the HIV antigens, the medium is rinsed in order to remove unbound antibodies and then placed in contact with a developer, which causes a colour reaction if antibodies have bound. The problem that arises with a screening test of this type is that each person presents an extremely wide and variable range of antibodies and that, occasionally, an antibody may bind to the medium in a non-specific manner. When this happens, a false positive result is obtained. To solve this problem, when there is a positive screening test, more complex and more costly confirmation tests are usually used to confirm the diagnosis. The confirmation test looks for all the reactive antibodies (which is known as "Western blotting") or specifically amplifies the viral genome (Polymerase Chain Reaction technology). The tests used are very sensitive in order to enable high-quality screening. This means that when the patient has the infection and has developed antibodies, the test will detect them. Above all, the aim is to not miss an infection. This high sensitivity does not, however, guarantee a high positive predictive value.

To be able to assess the sensitivity, the specificity, the positive predictive value and the negative predictive value of a screening test, it is necessary to compare its performance to that of an infallible confirmation test, an "absolute standard". Thus, the following possibilities are obtained for a screening test:

	Confirmation test	
Screening test	Positive	Negative
Positive	True positive (TP)	False positive (FP)
Negative	False negative (FN)	True negative (TN)

Where the *sensitivity* is equal to $\frac{TP}{TP+FN}$, as the probability that a patient who is truly positive is also found to be positive by the screening test;

the *specificity* is equal to $\frac{TN}{TN+FP}$, as the probability that a patient who is truly negative is also found to be negative by the screening test;

the *positive predictive value* is equal to $\frac{TP}{TP+FP}$, as the probability that a positive screening test indicates a genuine anomaly;

the *negative predictive value* is equal to $\frac{TN}{TN+FN}$, as the probability that a negative screening test excludes a genuine anomaly.

The current prevalence of HIV infection in Belgium is in the order of 1 in 1000. A screening test that detects all infected patients and only provides a false positive result one in 200 times (the value announced by a manufacturer for an excellent screening test) would provide the

following figures when it is used on 100,000 people, provided that the screening test is perfectly performed, in particular taking account of the period required for the appearance of antibodies (the "HIV window" period):

	Confirmation test		
Screening test	Positive	Negative	
Positive	100	499	599
Negative	0	99,401	99,401
	100	99,900	100,000

i.e. a sensitivity of $\frac{100}{100}$ = 100%

a specificity of $\frac{99,401}{99,990}$ = 99.5%

a positive predictive value of $\frac{100}{599}$ = 16.5%!!

a negative predictive value of $\frac{99,401}{99,401}$ = 100%!!

Therefore, with the current prevalence of HIV infection in Belgium, even an excellent screening test would provide a vast majority of ***false*** positive results (83.5%). Moreover, this is in line with the experience of clinical laboratories, meaning the vast majority of people with a positive screening test would be needlessly alarmed by this result. It is for this reason that, in Belgium, the result of a screening test performed by a laboratory is only in principle communicated to the requesting doctor or the patient after a second analysis of the sample with the confirmation test in a reference laboratory. In this way, any unnecessary panic is avoided.

The issue of false positives will be very different when this same screening test is used in a population presenting a very high prevalence of HIV infection (e.g. 30%). The following figures would then be obtained:

	Confirmation test		
Screening test	Positive	Negative	
Positive	30,000	350	30,350
Negative	0	69,650	69,650
	30,000	70,000	100,000

and a positive predictive value of

$$\frac{30,000}{30,350} = 99\%!$$

This data must be taken into consideration in assessing the acceptability of tests to be performed by oneself in Belgium. Given the low prevalence, the positive predictive value of such a test is actually limited. This means that, using the example, during the testing of 100,000 people 499 false positive results would be obtained. It is nevertheless necessary to set this against the

fact that 100 truly positive diagnoses and 99,401 truly negative diagnoses would be obtained during the testing of 100,000 people, provided that the test is correctly performed, taking account of the window period. Of course, we have to weigh the pros and cons of these results and explore whether it is possible to further reduce the number of false positives through further technical improvements.

d. Importance of the risk of stigmatisation and fear of stigmatisation

At the time of an HIV screening test, the possibility that the result of the test will be disclosed to third parties is often a major factor in avoiding testing, due to the risk of stigmatisation. Since AIDS was initially associated with (male) homosexuality, and with intravenous drug use, HIV infection and AIDS are still highly stigmatised. This is very clearly reflected then in the difference in the responses to HIV infection depending on whether it involves people infected by the transfusion of contaminated blood - who feel in no way responsible for the infection and on the contrary consider themselves "victims", they therefore admit their HIV-positive status publicly and lay claims against the "guilty parties" - on the one hand and people infected through sexual intercourse or through the use of contaminated injection tools on the other (drug addicts). The last two groups are deemed to be responsible for their misfortune and may not therefore count on the understanding and compassion of society. Doctors and professionals in the health care sector are of course trained to not let themselves be influenced by these factors.

The issue of HIV is therefore linked to a complex mix of interpersonal relationships in which sexuality, the feeling of guilt, regrets and social stigmatisation play a role that must not be underestimated. With regard to this risk of stigmatisation, cultural differences also play a major role.

e. Impact on behaviour

The impact of HIV screening tests on the behaviour of the people concerned is complex:

- In the case of HIV-negative status, the result means that the individual concerned is not infected (provided that the window period was properly taken into consideration). It remains essential, for preventive purposes, to avoid unsafe behaviour in the future. As this infection-free finding may give an individual the belief that the unsafe behaviour adopted previously is seemingly not so dangerous, there is a risk of seeing him or her continue this behaviour subsequently or develop a (irrational) feeling of "invulnerability".
- If the result is positive, it is particularly important that the person concerned does not place other people in danger through his or her subsequent behaviour and that he or she seeks the necessary treatment and support.

Given the complexity of interpretation and of the implications for prevention and treatment, as well as the major emotional impact of the diagnosis, it is essential to ensure appropriate assistance and guidance at the time of the communication of the test result. The recommendations for the best way to offer this assistance, before and after the tests, were clearly formulated in 1993 (Wetenschappelijke Stuurgroep Aids, 1993).

2. Testing possibilities

a. Current monitoring system in Belgium

In Belgium, 8 AIDS reference laboratories have been funded by the Ministry of Public Health in order to perform confirmation tests on positive sera. These sera are sent to the reference laboratories by local laboratories that have discovered a positive result. The result is provided to the patient's doctor, via the local laboratory, who communicates it to the patient. New cases are also reported using forms sent anonymously by the patient's doctor to the Board of AIDS reference laboratories, which guarantees the confidentiality of this data and processes it for epidemiological purposes.

It appears that the current system provides an almost complete picture of the number of people with HIV diagnosed in Belgium.

It is noted, however, that the frequency of HIV tests has decreased in recent years and that diagnoses are made at a later stage, such that there are calls for early testing in order to be able to more quickly adopt a preventive and curative approach (Sasse, 2001).

b. Self-tests to screen for HIV

HIV self-tests are screening tests and therefore require a confirmation in the case of a positive result. These confirmation tests cannot be performed by the user and must always be entrusted to experienced laboratory staff.

The traditional methods of HIV infection screening required a certain amount of time, but technical developments have made it possible to significantly shorten this period: the results are now known within a matter of minutes. The self-tests discussed below are among these "rapid tests". They are of satisfactory quality. Although there remains a difference in quality between rapid tests and traditional screening tests, this difference is less significant than in the past. Rapid tests have become extremely sensitive, such that false negatives have been virtually eliminated, leaving aside the window period - currently less than one month. This increased sensitivity nevertheless comes at the expense of specificity (up to 2% false positive results). As noted, in a country like Belgium, where the prevalence of HIV is 0.1%, the vast majority of positive tests are therefore false positives.

In the **definition** of van der Stappen and Ulenkate (1999) cited above (see I. CONTEXT), it is necessary make another distinction between **two types of self-tests**:

- "**True**" **self-tests** (home self-testing or home validated testing): the person concerned obtains these tests on his or her own initiative, personally carries out the processes necessary to use the test, reads the result and interprets it, without the intervention of a professional.

Self-tests to screen for HIV require correctly carrying out a certain number of steps and their use is therefore a little more complex than that of pregnancy tests, for example. However, the average citizen can usually use them without difficulty.

- **Home self-sampling tests** (home sample collection tests or home access testing): the person concerned places a blood sample on a coded medium and sends it to a laboratory. The laboratory performs the actual test (screening test and - if necessary - confirmation test) and the person concerned can call the laboratory after a few days in order to be provided with the result using the code. If the result is positive, notification is in any case handled by a qualified person who is ready to listen and provide the necessary support to the person concerned, as well as provide him or her with appropriate information. Demographic information is also requested at the time the sample is sent, without however the user's identity being disclosed.

The Advisory Committee interprets the request that was submitted to it as a request regarding the acceptability of self-tests in the strict sense, i.e. "**true**" **self-tests. Unless otherwise specified, this opinion therefore concerns these self-tests in the strict sense for HIV screening.** We nevertheless also address in passing Home Sample Collection (HSC) HIV tests as alternatives (and perhaps less controversial alternatives - see below) to "true" self-tests. The annex to this opinion contains more details on this subject.

The Advisory Committee cannot say with any certainty that these self-tests are currently marketed in Belgium, but they are in any case available via the internet. To the best of our knowledge, the use of self-tests to screen for HIV is currently very limited. Studies conducted in the United States show that the use of these tests is, in reality, considerably below the stated intention to use them (Colfax et al., submitted for publication).

c. Current legal situation

On 7 August 1996, a Draft Royal Decree banning in vitro diagnostic medical devices intended for the detection of HIV infection, to be used by the patient himself or herself, was submitted to the Higher Health Council. This Draft was then considered during a meeting of this council on 25 October 1996. The Higher Health Council subsequently made a number of observations (opinion issued on 13 December 1996). It in particular recommended that these devices be used by professional users (laboratories).

This Draft Royal Decree was at the same time notified (on 7 October 1996) to the European Commission (since it concerned a technical measure likely to impede the free movement of goods). In a telex of 11 December 1996, the European Commission notified that it deemed the proposed measure to be disproportionate to the objective to be achieved: no distinction was made between the people who could use these devices and it was a general ban that was being proposed. The Commission also noted that a draft Directive on in vitro diagnostic medical devices had been submitted. A response period was provided until 11 April 1997.

A decision was made to abandon the Draft Royal Decree and to await the adoption of the Directive on in vitro diagnostic medical devices. This Directive 98/79/EC was finally adopted on 28 October 1998 (OJ, 7 December 1998). It is aimed at technical harmonisation and standardisation within the EU.

On 20 December 1999, a new Draft Royal Decree was submitted to the Higher Health Council to ban the offering for sale, making available or distribution to the public, whether in return for payment or free of charge, of in vitro diagnostic medical devices intended for the detection of HIV infection, as well as the importing of these same medical devices by private individuals.

The Higher Health Council issued a favourable opinion on 16 October 2000.

The Draft was submitted to the Council of State on 20 November 2000 for an opinion (with a request for the utmost urgency).

In its opinion, the Council of State considered that the measure was not proportional to the objective sought and that distribution to the public should nevertheless be permitted, subject to strict conditions.

Meanwhile, the Royal Decree transposing the European Directive on in vitro diagnostic medical devices into Belgian law had been published (Royal Decree of 14 November 2001 on in vitro diagnostic medical devices, Belgian Official Gazette of 12 December 2001). This Royal Decree provides that after a transitional period, and at the latest from 7 December 2003, in vitro diagnostic medical devices must bear the CE mark.

Article 5, § 7 of this Royal Decree authorises the Minister responsible for Public Health to subject the distribution and delivery of a specific in vitro diagnostic medical device, intended for self-diagnosis, to special conditions or to ban it on public health grounds.

On the basis of the Royal Decree of 14 November 2001, the Minister of Public Health prepared a Draft Decree making in vitro diagnostic medical devices intended for the detection of HIV infection, to be used by the patient himself or herself, available only on prescription and reserving distribution for pharmacists. This Draft was submitted to the Council of State on 10 June 2002 for an opinion.

It should also be pointed out that other Member States have taken restrictive measures in respect of these devices, e.g. the Netherlands: made available to the user on condition that sufficient information is provided and of distribution solely via pharmacies (Borst-Eilers, 2000).

II. ETHICAL ASPECTS OF THE USE OF SELF-TESTS TO SCREEN FOR HIV INFECTION

A. Opinion of the external experts consulted

The experts consulted (virologists, doctors and patient representatives) are not in favour of the introduction of self-tests to screen for HIV and do not support their use. While self-tests present a certain number of benefits in terms of accessibility and respect for privacy, the experts draw attention to the following points:

- on a technical level, the frequency of false positives;
- the current testing system is well developed as regards the protection of privacy, diagnostic certainty and accessibility; therefore, it is not expected that the making available of self-tests will result in an increase in the total number of people tested, or that it will help reach groups not tested to date;
- the necessary guidance and assistance are lacking in the case of self-tests, as much in terms of the correct interpretation of the test result, the emotional impact, referral for treatment or the administration of the latter, as in terms of the implications of the test result as regards prevention (e.g. creation of a false sense of security in the case of a negative result);
- the increased risk of inappropriate use of the test (job application, police, etc.);
- the loss of epidemiological data.

However, it is noted that Home Sample Collection (HSC) tests give rise to considerably fewer problems.

It is the opinion of a few experts that many improvements should be made to the existing system, in particular with respect to the communication of results and the guidance and counselling relating to these results.

B. Discussion of the ethical arguments

1. Arguments in favour of self-testing

a. Autonomy of the individual

Among the favourable arguments put forward, there is the point of view that self-tests are a means of expressing the autonomy of the individual, so the principle that any person wishing to perform an HIV self-test may do so. In this context, and supposing the availability of this technology, it is important to point out that the approach would undoubtedly exist alongside the current resources available and would not therefore replace the existing testing structures. The user would thus be offered an additional option - which could be considered an increase in the autonomy of the individual.

b. Accessibility and speed

The accessibility of the test and the speed of the result are two additional benefits of self-tests. Speed helps to reduce the period of uncertainty and it is possible to act quickly on the basis of the test result, in particular as regards the changing of behaviour for the purpose of prevention.

Accessibility theoretically enables earlier treatment, and proper treatment is critically important, especially during the early months in order to better preserve the patient's immunological resources. This approach provides better results than the old "eradication concept".

c. Privacy

The possibility of performing the test at home, with total privacy, is important when the person in question is too frightened or embarrassed to seek outside help. This situation may occur in countries or regions where HIV infection still carries a considerable social stigma. There still also remains a risk of stigmatisation in Belgium: this perhaps explains why some people do not have themselves tested and are therefore unaware of their HIV-positive status.

d. Simplicity of use and sensitivity

The test is inexpensive: based on what is known, its price is approximately 20 euros. This argument must nevertheless be viewed with some caution because the low costs of the test can mainly be explained by the fact that the costs of guidance and counselling are not included in the price. The tests are undoubtedly a little more complex than pregnancy tests, but remain simple to use for any individual with normal intellectual abilities. The tests have a high sensitivity: in the case of a negative result, an infection-free status is almost certain (provided that the HIV window has passed). Despite its high sensitivity, the test is of limited clinical value in the context of low prevalence of the disease since in the end it is the positive predictive value of the test that is critical in practice. The latter (see I.B.1.c. above) is in any case relatively low in the context of the current prevalence in Belgium.

e. Reaching groups not tested to date?

One key question remains, namely whether the making available of self-tests would lead to an increase in the number of (early) HIV infection diagnoses - because individuals who do not currently have themselves tested would use these self-tests. The experts consulted consider that this would not be the case, but no specific arguments have been put forward. It was, for example, stated that IV drug addicts are less concerned about the risk of infection due to their enslaving addiction. One cannot, however, conclude from this that they would not be more inclined to use self-tests - if they were available - rather than the existing system. Nevertheless, a study conducted in the United States concerning HSC tests and not "true" self-tests suggested that this consequence is indeed plausible (Branson, 1998; Philips e.a., 1995; JAMC, 2000).

It is nevertheless necessary to note on this subject that this data must be interpreted in the light of the situation in the United States, where care is much less personalised and more costly than in Belgium.

2. Arguments against self-testing

a. Emotional response caused by isolation

One of the arguments raised against making self-tests available concerns the isolation characterising the performance of the test: this can give rise to a feeling of fear that is difficult to control and that in some cases can result in a desperate act. Moreover, this negative point is compounded by the high risk of false positives. In this regard, it should be recalled that in medical practice a positive test is always followed by a confirmation test (Western blot) performed in a reference laboratory. Thus, there is total or almost total certainty of obtaining a true positive result before notifying it to the person in question.

According to a study on the emotional impacts of the notification of "suspected" results in the context of cancer screening, it also appeared that this emotional burden was significant, even when subsequent tests yielded a negative result (Lerman et al., 1991).

The risk of uncontrolled or dangerous emotional responses clearly cannot, moreover, be ruled out. Given this risk, experts recommend seeking the help of a person of trust for assistance at the time of notification of the test result. Specifically, the emotional burden borne at this time is

such that the person in question barely understands the information provided. However, according to a study, care staff overestimated the possibility of uncontrolled emotional responses (Spielberg, et al., 2001). The study also showed that an increased risk of suicide is in particular associated with the appearance of the *symptoms* (of AIDS) rather than with learning of the *diagnosis*.

Some members of the Advisory Committee believe that individuals are capable of assessing the social support that they need and of making the necessary arrangements for this purpose. According to a study conducted in the United States on the communication of the results of Home Sample Collection (HSC) tests, users were not usually alone when they called to obtain the result by telephone (Branson, 1998). It is expected that a self-test user will therefore also ensure that a person of trust is present with him or her or will at the very least ensure that he or she can contact one. Others members believe that a doctor is the most suitable person to act as the person of trust.

b. Lack of guidance and counselling

One of the main deficiencies of self-testing (relating to its private and confidential nature, see the arguments in favour set out above) concerns the lack of guidance and counselling, both before taking the test (which can lead to unnecessary overconsumption by anxious people with no unsafe behaviour) and at the time of notification of the result. The patient is alone when he or she is facing a potentially positive result and a good opportunity is lost to propose a treatment pathway, which is important, especially during the early months, in order to better preserve the patient's immunological resources. The opportunity to provide counselling to ensure that safer sex is practised is also lost.

Isolation is an issue even if the result proves to be negative because it is presumed that most of the people who use a self-test have taken risks: a test therefore provides a good opportunity to properly inform these persons and make them aware of the risks inherent in their behaviour. The use of self-tests can therefore be detrimental to preventive measures in the sense that, even though this method offers good reliability, it may lead to making unsafe behaviour more widespread.

Based on the experience gathered within patients' associations, persons who benefit from effective treatment from the outset manage to lead a more or less normal life much more quickly than individuals who are forced to overcome the initial phase of this ordeal alone.

During the discussion, certain members of the Advisory Committee made various observations:

- Guidance and counselling on preventive behaviour are clearly critical and it is necessary to provide sufficient options in this regard. The question nevertheless arises of whether the moment when the result is announced is in fact the most appropriate time: the information provided then is not (fully) understood. For this reason, each notification of bad news is in principle linked to an appointment for a follow-up meeting.

- Furthermore, it is important to point out that the context of self-tests must be compared to the "ordinary" guidance and counselling offered, and not to an imaginary ideal situation. Here, the outcome of a study on the subject indicates that this guidance and counselling are not the ideal reference framework. In the North American context, a study by Farber et al. (1996) showed that the notification of the diagnosis was often entrusted to people who were not very qualified and an infringement of privacy was reported in approximately a quarter of cases; 47% of the persons asked received little - if any - information during the subsequent guidance and counselling session (post-counselling) and 39% declared having received poor or non-existent emotional support when the test results were communicated. Even in a standard testing situation, which usually involves guidance and face-to-face counselling at the time of notification of the results, 17% of diagnoses were communicated by telephone and 16% by post (Bayer et al., 1995), while more than half of the persons tested received no assistance (Ocamb, K., 1994; Mosen et

al., 1998). When this guidance and counselling are provided, they consist of a 20-minute session (on average) for positive tests and a 10-minute session for negative results (Doll & Kennedy, 1994).

- Very little empirical data exists on the manner in which guidance and counselling currently take place in Belgium. The information provided by patients' associations clearly demonstrates that the potential risks of self-tests cannot be compared to an unrealistic ideal situation:

    - There is strong criticism of the many tests that are performed in hospitals at the time of surgical procedures, the result of which is apparently often not even consulted by the requesting doctor. Patients may then feel a false sense of security: they presume that there is no problem, given that they have not been told anything.
    - Considerable efforts, with an emphasis on continuous training, are being made regarding the involvement of attending physicians in the HIV issue, but continued attention must certainly be paid to this point.
    - Some doctors still communicate the result of the initial test (screening test) without knowing that of the confirmation test - which is usually available 48 hours later. The patients' associations consider the notification of only one result, namely that of the confirmation test, to be a minimum requirement.
    - Patients associations also want the test to remain a free choice. Some people, for example, adjust their behaviour in order to avoid potential infection but choose not to have themselves tested. Some patients have been tested without having given their consent, during admission to a hospital for a routine procedure, which is a reprehensible practice.
    - Patients' associations note that there are usually no problems when interaction with the attending physician is positive. Once more, however, it comes back to the issue of young people, who experience difficulties in discussing this issue with their parents and their family doctor (who is often their parents' doctor), and who are sometimes unaware that this doctor is bound by rules of confidentiality with respect to the young person's parents. Hence the great importance of organisations such as youth advisory centres and family planning and sexual education centres: they aim to facilitate the process for young people by offering them a free test. Continuous training for general practitioners is of course essential, but a change of attitude is also required. Several factors play a role here: insufficient familiarity, lack of time, fear of being "caught up" in a wider problem. The experience acquired has nevertheless led patients' associations to observe that, when they initiate a dialogue with attending physicians for whom the initial contact with an HIV-positive patient did not go well, a positive turnaround often takes place in the short term. It is important to note that the support offered to HIV-positive patients involves a *team effort*. The ever increasing complexity of therapies also requires good cooperation between specialist services and the attending physician. Patients' associations have noted positive experiences in the area of continuous training of doctors by other general practitioners who have already treated HIV-positive patients. Furthermore, the guidance offered is following developments in treatment: there is for example an increasing number of questions on the side effects of medications, possibilities for part-time working, etc.

It is the opinion of some members that the arguments put forward under points *a.* and *b.* appear to go back to the same ethical question: namely determining whether a person can bear the risk of being faced with an emotionally overwhelming result without assistance. These members tend to work on the premise that a person may actually decide to run this risk provided that he or she has received all the information required to correctly interpret the result of the test and that he or she is sufficiently informed about the risk and the implications of the test result (in preventive and curative terms), whatever it may be, also for the purpose of protecting third parties.

The experts on the day-to-day treatment of people infected with HIV state that these conditions are practically never met. It is their opinion that health-related fears can only be dealt with in an optimal manner through an open and constructive dialogue.

c. Commercialisation

A third opposing argument concerns the creation of a commercial circuit making it possible to divert financial resources to a non-essential medical service, to the detriment of collective health care. If we take the example of a pregnancy test, we note that, in most cases, this self-test does not replace the pregnancy test performed in a laboratory but that it is complementary. If the result of the self-test is positive, the person concerned will in the best-case scenario request a verification test performed by a laboratory (which, moreover, is a necessary step). If the result is negative, she will often as a second resort turn to the laboratory test, because it is more reliable and she is wondering whether the negative result is due to a possible error in the use of the pregnancy test.

The commercialisation risk relates to the promotion of pharmaceutical products. Specifically, the greater the freedom in this area, the more aggressive the marketing activities of pharmaceutical companies, which may lead to unnecessary consumption, i.e. many individuals who do not engage in unsafe behaviour will be unnecessarily encouraged to use self-tests.

The possibility of easily obtaining the test outside the medical sphere also comprises a risk of misuse by third parties (employers, insurers, police services, etc.): these tests could be used in "semi-clandestine" conditions or in situations involving the violation of medical confidentiality. In this context, self-testing could paradoxically become a threat to the confidential nature of personal medical data, even though it is considered to be a means of obtaining medical data while ensuring the utmost respect of the right of individuals to privacy and confidentiality.

According to certain members, the arguments concerning commercialisation and the risk of misuse do not significantly differ between self-tests and traditional tests. As these members affirm, the majority of tests are performed at the request of the patient and the fact that they are negative in 99.5% of cases (Devroey, 2001) appears to indicate that attending physician does not refuse to perform the test - even when it is apparently not justified on any (medical) grounds. Testing is then driven by fear (and who has the right to claim that this is not a "legitimate" reason?) or, possibly, by a hidden demand from a third party who is putting pressure on the patient. A self-test can just as easily be used in this type of situation - since the cost has been incurred in any case. It is also to be expected that the customer will pay for self-testing himself or herself and that its costs will not be imposed on the community.

d. Exploitation of the feeling of fear

Given the future increase in the number of self-tests available, some warn that these tests exploit in particular the fear of a section of the public, i.e. psychologically vulnerable people are most likely to become victims of marketing campaigns to promote these different self-tests. For others, this assumption overlooks scenarios involving a rational and responsible use of the available resources.

e. Loss of epidemiological data

Finally, it is necessary to point out that the use of self-tests makes the collection of epidemiological data more difficult. This data is currently placed in the database of the reference laboratories. This difficulty may be partly overcome using a cross-sectional study strictly focusing on the collection of epidemiological data, even if there is a major risk of this study disregarding certain specific smaller populations. To the extent that these persons cannot (any longer) turn to existing medical structures for the detection of their HIV-positive status and therefore use self-tests, much information relating to the epidemiological evolution of the

condition is lost.

3. Observation regarding HIV Home Sample Collection (HSC) tests

As specified elsewhere in the document (and in the Annex to this opinion), the objections made against self-tests are considerably less numerous in the case of HSC tests. There is, however, a practical problem. Belgian virology laboratories (including the reference laboratories) are competent for the performance and interpretation of tests but, unlike human genetics centres, they do not have an infrastructure to provide guidance and counselling to the patient. The guidance and the counselling of the patient is part of the role of the doctor requesting the test, and it is highly unlikely that clinical laboratories are able or wish to take on the task of providing personal guidance and counselling. It should be considered in greater depth whether a clinical laboratory may analyse a blood sample for diagnostic purposes without a request from a doctor. In any event, the test will not in this case qualify for reimbursement by the National Institute for Health and Disability Insurance (INAMI). If the clinical laboratory also has to provide and support a guidance and counselling function, there is a high risk of the package becoming unattractive to potential customers from a financial point of view. From a practical point of view, the concept of home sampling therefore hardly appears feasible in Belgium.

III. CONCLUSION & RECOMMENDATIONS

The Advisory Committee on Bioethics agrees on the critical importance of an appropriate screening policy, both to promote early treatment for HIV-positive persons and to tackle the epidemic.

As regards the potential introduction of self-tests to screen for HIV infection, it acknowledges that making such tests available:

- would strengthen the autonomy of users;
- in principle helps to rapidly diagnose HIV infection, which would promote early preventive and curative intervention - again in principle (there is a risk of facing the opposite situation in reality);
- reduces the risk of stigmatisation (inherent in the involvement of third parties at the time of the test);
- may prove to be extremely helpful in regions characterised by a high prevalence and/or a less well developed system of professional diagnosis.

On the other hand, the Committee raises the following key arguments against the introduction of such tests in Belgium:

- the high rate of false positives given the low prevalence of HIV infection in Belgium;
- the lack of competent guidance at the time of the test, which may give rise to dramatic emotional responses in the case of positive test results (and false positives) and also reduces the ability to obtain the advice of an expert regarding prevention and treatment;
- the commercialisation of an unnecessary diagnostic tool, while there is great accessibility to traditional tests;
- the risk of misuse of the test (by police services, insurers, etc.);

- the exploitation of fear for profit;

- a significant loss in terms of epidemiological data on (the evolution of) the epidemic.

Some members of the Advisory Committee therefore consider that the arguments against the introduction of self-tests carry more weight and as such believe that they should declare themselves against the introduction of these self-tests. Other members, however, support the point of view that one should not be too quick to consider the potential users of self-tests to be incapable and irresponsible individuals. Rather, they argue in favour of a *precise determination of the conditions* under which self-tests could be used responsibly, in order to be able to strive towards fulfilling these conditions:

- the user must be aware that finding out the test result carries a significant emotional burden and must ensure that he or she receives the necessary social/emotional support;

- the user must know that false positive results are possible and be aware of what they mean;

- the user must be aware of the preventive and curative implications and know where and how to seek the help of specialists.

This less negative position is also based on the doubts expressed regarding the opinion of the experts, according to whom making self-tests available would not result in the greater/quicker use of the tests within certain groups.

The Advisory Committee further stresses the following points:

- the guidance offered to the users of HIV tests must be optimised in all cases;

- a scientific study prior to any introduction of self-tests covering a wide range of issues relating to HIV tests is essential (factual data on the emotional responses to the test result and effects on preventive behaviour, use of tests, provision of guidance and counselling, etc.);

- the majority of the objections raised against the use of self-tests in the strict sense do not apply to home self-sampling tests (home sample collection - HSC): these tests offer many of the advantages of self-tests, but without most of the disadvantages.

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The opinion was prepared by select commission 2000/1, consisting of:

Joint chairpersons	Joint reporters	Members	Member of the Bureau
G. Rorive	A. Dieudonné	P. Cosyns	Y. Englert
J. Vermylen	J. Vinck	G. Verdonk	

Member of the secretariat
L. Dejager

Experts interviewed
M. Van Ranst, professor at KUL, Leuven
N. Clumeck, professor at ULB, Brussels
P. Reyntiens, representative of the non-profit organisation Sensoa (association of Flemish organisations active in combating AIDS
E. Geeraerts, assistant advisor at the Pharmaceutical Inspectorate of the Ministry of Social Affairs, Public Health and Environment

Experts consulted

The working documents of the select commission– the question, personal contributions of the members, minutes of the meetings, documents consulted – are kept on file at the Committee's Documentation Centre where they are available to be consulted and copied.

The opinion is available to be consulted at **www.health.belgium.be/bioeth**

Annex to opinion no. 17 of 10 June 2002

Limited review of the literature concerning HIV Home Sample Collection (HSC) tests

We offer here a short reasoned bibliography, which is mainly based on Medline, concerning the use of home sampling collection (HSC) tests to screen for HIV. The majority of the studies with a direct interest in the subject originate from the United States, and a certain number of them were conducted in the context of discussions surrounding the approval of these tests by the FDA. The fact that these are primarily US studies must of course be taken into account when applying the conclusions to the Belgian situation. However, it is necessary to bear in mind that the impact of cultural differences must be weighed against the benefit inherent in the availability of data extracted from an empirical study, which is not the case of Belgium for the majority of the points.

The major differences between HSC tests and "true" self-test are as follows: (1) critical elements in terms of performance and interpretation, including subsequent verification of an initial positive result, are handled by professionals and not by the user; (2) telephone support is part of the standard procedure, even more so in the case of a positive result; (3) the recording of relevant data in the context of an epidemiological study remains possible.

According to the research, HSC tests did not give rise to serious problems with regard to the technical aspect or use (Bayer et al., 1995; Frank et al., 1997; Osmond et al., 2000).

In practice, the extent of the use of these tests was lower than the reported intentions of potential users suggest (Colfax et al., going to press). The main reasons put forward to explain the non-use of the tests are: doubts regarding the reliability of the test (56%), lack of guidance and counselling (47%), price (34%). As the above-mentioned studies show, the primary reason for non-use (doubt with respect to reliability) is unjustified.

A few key questions are discussed in greater depth.

1. *Does the availability of HSC tests make it possible to reach groups that would probably not be tested in the absence of these tests*?

The answer is undoubtedly yes: groups that use HSC tests present a different risk model, in the sense that they are more exposed to risks of infection through heterosexual contact; homosexuals and IV drug addicts make greater use of traditional tests (JAMC, 2000). The groups that are under-represented in traditional prevention campaigns show not only a greater interest in this type of test (Phillips et al., 1995), but also use it much more frequently (Bayer et al., 1995; Branson, 1998). It is therefore false to claim that the least-tested groups have only the *intention* to use HSC tests. *In reality*, they use them much more often than other population groups.

The study by Branson (1998), which was based on all the HSC tests performed in 1995 and 1996 (N=174,316), also noted that the number of positive results relating to HSC tests was higher than the number recorded in traditional testing locations. It can therefore be concluded that these tests actually do reach another group, which is exposed to increased risks.

2. *Is/are the feasibility of guidance and counselling or/and the quality of guidance and counselling reduced in the use of HSC tests?*

In the context of HSC tests, telephone support replaces the traditional face-to-face support. The negative impacts that may be linked to this lack of genuine guidance and counselling are one of the reasons that discourage potential users (Colfax et al., submitted for publication) and are a

significant factor in the discussion on the appropriateness of making these tests available. The fact that the lack of genuine guidance and counselling could give rise to intense emotional responses in the case of a positive result, that any possibility of passing on appropriate prevention messages is lost, and that referral to various therapeutic alternatives cannot take place or is insufficient, constitutes a justified concern.

Do the users of HSC tests take the initiative of calling the laboratory to find out the test result? The answer is yes for 97% of users; this result is higher than that for conventional testing locations (Branson, 1995). Bayer et al. (1995) also point out that 1 person in 3 having performed a test via a traditional channel did not return to be informed of the result. Furthermore, there is a significant difference between how therapists and users belonging to high-risk groups view telephone support: while the majority of therapists were convinced that users prefer traditional guidance and counselling (office-based), it was nevertheless the case that 73% of the individuals in this high-risk group have a preference for telephone support (Spielberg et al., 2001).

Do people who have a positive test result agree to be referred to medical and psychosocial therapists by means of telephone support? Some 65% agreed to be referred, 23% had already contacted therapists and 12% were already undergoing treatment (Branson, 1995). This is of course reported data.

3. *Is the risk of intense emotional responses, or even suicide, higher in the context of HSC tests (with communication of the result by telephone and telephone support)?*

Branson (1995) reports a certain number of worrying responses caused by a positive diagnosis: 7% of the people concerned stated that they were in a state of emotional shock, 5% discontinued telephone contact forthwith and 1 person in 610 reported suicidal thoughts, yet said that that he or she was not alone when the diagnosis was communicated.

These emotional responses certainly warrant our attention. Nevertheless, if one wishes to take them into consideration in assessing the acceptability of HSC tests it is necessary to take the following factors into account: (1) they are relatively rare and plans to commit suicide are no more common among HIV-positive persons than HIV-negative persons (Grassi et al., 2001) - they are often overestimated because studies do not apply control conditions (Mishara, 1998; e.g. see Kalichman et al., 2000), (2) therapists generally tend to underestimate the emotional capacity of patients to hear bad news and overestimate disadvantages of HSC tests for users (Spielberg et al., 2001), (3) the risk of suicide among AIDS patients is indeed higher but the actual rate of suicide is no higher when *the diagnosis is communicated* than that generally observed in the population - it increases, on the other hand, when *the symptoms of AIDS appear* (Starace, 1993; Dannenberg et al., 1996; Kelly et al., 1998).

Do users have the information and knowledge required to understand the results and properly assess the implications - particularly with regard to prevention? As regards the informative aspect of guidance and counselling, Frank et al. (1997) point out that at the end of the preliminary guidance and counselling session (pre-counselling) users possessed sound and sufficient knowledge to validly interpret the test results and the implications for prevention: users provided correct answers to 96% of the questions asked.

Conclusion

As far as it is possible to judge from the outcomes of the studies conducted in the United States, there are no grounds to discourage the use of HSC tests. This use must, however, be subject to a certain number of conditions. A study must also be set up as soon as possible to assess and accurately monitor the consequences of making these tests available.

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